

Claims

1. A pharmaceutical composition intended for topical use, which composition is in the form of an opaque emulsion-gel and which composition comprises

- (a) 0.02-0.4% (w/w) of diclofenac sodium salt,
 - (b) at least 50% (w/w) of water,
 - (c) 0-30% (w/w) of at least one C2-C4-alkanol,
 - (d) 3-20% (w/w) of a glycol solvent selected from the group consisting of propylene glycol and polyethylene glycol (200-20000),
 - (e) 0.2-3% (w/w) of at least one gelling agent selected from the group consisting of carbomers,
 - (f) 2-8% (w/w) of at least one lipid forming the oily phase of the emulsion-gel,
 - (g) 1-5% (w/w) of at least one non-ionic surfactant, and
 - (h) a basic agent selected from the group consisting of ammonia, sodium hydroxide and potassium hydroxide to adjust the pH of the total composition to 6.5-8;
- with the proviso that said composition is devoid of an antifungal drug.

2. A composition according to claim 1, which comprises

- (a) 0.05-0.3% of diclofenac sodium salt,
- (b) 60-92% of water,
- (c) 0-25% of ethanol, isopropanol, or mixtures thereof,
- (d) 3-20% of propylene glycol,
- (e) 0.3-2% of at least one gelling agent selected from the group consisting of carbomers,
- (f) 3-7% of at least one lipid forming the fatty phase of the emulsion-gel,
- (g) 1-3% of at least one non-ionic surfactant, and
- (h) ammonia to adjust the pH of the total composition to 6.5-8.

3. A pharmaceutical composition intended for topical use, which composition is in the form of an opaque emulsion-gel and which composition consists essentially of

- (a) 0.02-0.4% (w/w) of diclofenac sodium salt,
- (b) at least 50% (w/w) of water,
- (c) 0-30% (w/w) of at least one C2-C4-alkanol,
- (d) 3-20% (w/w) of a glycol solvent selected from the group consisting of propylene glycol and polyethylene glycol (200-20000),

- (e) 0.2-3% (w/w) of at least one gelling agent selected from the group consisting of carbomers,
- (f) 2-8% (w/w) of at least one lipid forming the oily phase of the emulsion-gel,
- (g) 1-5% (w/w) of at least one non-ionic surfactant, and
- (h) a basic agent selected from the group consisting of ammonia, sodium hydroxide and potassium hydroxide to adjust the pH of the total composition to 6.5-8.
4. A composition according to claim 1 or claim 3, wherein the polyethylene glycol (200-20000) usable as component (d) is polyethylene glycol (200-1000).
5. A composition according to any one of claims 1-4, which comprises (c) in an amount of from 5 up to 25% and (d) in an amount of from 3 up to 7% of the total composition.
6. A composition according to any one of claims 1-4, which comprises (c) in an amount of from 0 up to 5% and (d) in an amount of from 3 up to 20% of the total composition.
7. A composition according to any one of claims 1-4, which comprises (c) in an amount of from 0 up to 5% and (d) in an amount of from 3 up to 7% of the total composition.
8. A composition according to claim 6 or claim 7, which is devoid of the component (c).
9. A composition according to any one of claims 1-7, which comprises as C2-C4-alkanol (c) isopropanol.
10. A composition according to any one of claims 1-9, which comprises as gelling agent (e) carbomer 980, carbomer 940, carbomer 981, carbomer 941, carbomer 974, carbomer 934, carbomer 910, or a mixture of any of said carbomers.
11. A composition according to any one of claims 1-10, which comprises as lipid (f) either a mixture of paraffin and C6-C12-alkanoic acid C12-C18-alkyl esters, or a mixture of isopropyl myristate and C6-C12-alkanoic acid C12-C18-alkyl esters.
12. A composition according to any one of claims 5-7, which comprises as lipid (f) isopropyl myristate.

13. A composition according to any one of claims 1-12, which comprises as non-ionic surfactant (g) a polyoxyethylene (10 to 30) fatty alcohol ether.

14. A composition according to any one of claims 1-13, which is devoid of a chemical stabilizer.